PRINCIPAL/OVERALL INVESTIGATOR
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PROTOCOL TITLE
Improving Comprehensive Cancer Screening Among Vulnerable Patients Using Patient Navigation as part of a Population-Based Health IT System: A Randomized Control Trial

FUNDING
Lazarex Cancer Foundation
Harvard Medical School Center for Primary Care
Departmental Funds: MGH Center for Community Health Improvement

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October 9, 2014

SPECIFIC AIMS
Concisely state the objectives of the study and the hypothesis being tested.

In 2011, the MGH Laboratory of Computer Science and researchers from the General Medicine Division designed and implemented the TopCare system (Technology for Optimizing Population Care in A Resource-limited Environment) for comprehensive cancer screening across the MGH primary care network (IRB Protocol # 2009P002079). As part of this population management system, patients at high risk for not completing cancer screening are identified and referred to a patient navigation (PN) program.

Though PN is a part of the TopCare system, its effectiveness has not been formally evaluated. We will modify our existing health information technology (IT) platform to improve the automatic identification of patients who may be at increased risk for non-adherence with screening recommendations, and thus who may benefit from PN, so we can directly test the hypothesis that patient navigators using the TopCare system can improve breast, cervical, and colorectal cancer (CRC) screening rates within a primary care network. We will test this hypothesis in a randomized clinical trial of preventive cancer screening within the Massachusetts General Primary Care Practice-Based Research Network (MGPC-PBRN).

We define the following Specific Aims to address our primary study hypothesis:

Specific Aim 1: To modify and improve the existing automated algorithm utilized by TopCare to identify patients who may benefit from PN.

Specific Aim 2: To conduct a randomized trial of the TopCare PN program within our PBRN assessing the impact of PN on cancer screening rates in eligible patients.
Specific Aim 3: To assess the impact of PN on satisfaction with overall medical care.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

PN has been shown to improve cancer care and decrease disparities in vulnerable populations. At Massachusetts General Hospital (MGH), all cancer PN programs are located at MGH Chelsea HealthCare Center (HC) and focus on a single cancer for a defined episode of care. However, internal data shows that over 10,000 patients overdue for cancer screenings and potentially benefiting from PN may be overdue for more than one type of cancer screening or receive care outside of MGH Chelsea HC.

In 2011, the MGH Laboratory of Computer Science and researchers from the General Medicine Division designed and implemented the TopCare system (Technology for Optimizing Population Care in A Resource-limited Environment) for comprehensive cancer screening across the MGH primary care network. This novel population-based IT system identifies all patients within the network eligible and overdue for breast, cervical, and/or colorectal cancer screening. Clinicians are presented with real-time, relevant clinical information about their patients and can choose to send reminder letters to patients about screening, refer them directly to practice delegates for phone follow-up or to PN for more intense outreach, or defer screening. The IT system also has an automated component for clinicians who do not review their roster of overdue patients in a timely manner. Reminder letters to overdue patients are automatically sent, and the system moves them to practice delegate rosters for follow-up. If the patient remains overdue for screening and the patient is identified to be at high risk for non-adherence (determined by an algorithm involving number of overdue tests, age, primary language spoken, and no-show visit history), the system moves them to a patient navigator roster.

Though PN is currently included as a component of the TopCare system, it has not been formally tested. Specifically during the TopCare randomized clinical trial (IRB Protocol # 2009P002079), PN was not available for the first 4 months of the study, and high risk patients were not randomly assigned to PN or not. Thus, we were unable to evaluate whether PN is effective for multiple cancer screenings among vulnerable patients across an entire practice network.

In this proposal, we seek to utilize our valuable PN resources by improving our automated identification of patients who are most in need of PN and by formally testing if patient navigators using the TopCare system can improve cancer screening rates among vulnerable patients across the MGH primary care network. We also seek to test whether a positive PN experience impacts patients’ overall satisfaction with medical care. Evaluating the patient experience with PN is also important because, as an extension of the health care system, patient's experiences with PN (positive or negative) may directly impact their views of the health care system a whole.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site
It is important to note that the TopCare system is currently the standard of care in the MGPC-PBRN. As such, this proposal does not involve evaluating the TopCare system or the patients and providers using it. Rather, the study will evaluate the part of the TopCare system that involves the automated identification and referral to PN of patients at increased risk of screening non-adherence. All eligible patients overdue for cancer screening tests will receive usual care that includes a reminder letter and referral to a scheduling delegate for follow-up. Since the TopCare system represents usual care for patients with the MGH primary care network, no patient contact will occur solely for research purposes. The study will involve randomly assigning patients overdue for screening and identified as high risk for not completing screening to early or delayed PN. We believe this random assignment is ethical because PN is an extremely limited resource, and all patients in our network identified as high risk for not completing screening could not be contacted by our navigators in a short period of time. Thus we will randomly assign access to PN during the study period, and then allow all patients to be navigated after the study period is over. As a result, all overdue, high risk patients will be referred for PN, but the timing of the referral will be randomly assigned. In this study, our objectives are to improve our algorithm to automatically identify patients who are more likely to benefit from PN (Specific Aim 1), and to evaluate the clinical impact of PN in a randomized controlled trial within our MGPC-PBRN (Specific Aim 2). We will also survey all patients identified by the TopCare algorithm to assess their overall satisfaction with healthcare to determine whether PN impacts satisfaction with healthcare (Specific Aim 3).

Revising and improving our current ‘high risk’ algorithm to automatically identify patients who may be helped by PN in Specific Aim 1 will help us to most effectively utilize our limited PN resources. The current algorithm utilizes information about patient age, number of overdue tests, primary language, and no-show visit history. We will investigate adding patient registration information about insurance and education status to better identify patients at high risk for not completing screening.

In Specific Aim 2, we will randomize eligible patients from our MGPC-PBRN primary care practices to either Arm 1 – TopCare with PN: Patients identified as at high risk for not completing screening by our automated algorithm will be assigned to a PN list for contact to help schedule and complete screening (breast, cervical, and colon), or Arm 2 – TopCare without PN: These patients will benefit from the standard features of the TopCare system, including automated identification of overdue patients, patient reminder letters, and referral to a scheduling delegate. All high risk patients in this arm will be eligible for PN after the study period is over.

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<th>Intervention</th>
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About 800 of the patients deemed by the ‘high risk’ algorithm to be at high risk of not getting screened will be randomly selected to be placed on PN TopCare list to be navigated.

About 1600 of the patients deemed by the ‘high risk’ algorithm to be at high risk of not getting screened will be randomly selected to receive usual care during the study and will then be eligible for the intervention after 9 months.

In Specific Aim 3, we will employ previously-validated surveys to evaluate whether PN impacts patient satisfaction with medical care.

**Eligibility Criteria:**
All patients within the MGPC-PBRN who are eligible for breast, cervical, and colorectal cancer screening and are identified as being at high risk for not completing cancer screening.

- **Inclusion criteria:** Adult patients ages 21-75 seen in MGPC practices in the past 3 years, and 1) linked to a specific PCP, or 2) linked to a specific practice (for patients who are not linked to a specific PCP)

- **Exclusion criteria:** Patients who are 1) subsequently identified as having died prior to the study intervention using the Social Security Death Index, or 2) listed in the MGH registration system as having a PCP outside of the MGPC-PBRN network. Patients 76 years of age or older are excluded because cancer screening may not be appropriate due to other medical problems that are more prevalent with increasing age and because less information is available on the benefits of routine screening in older individuals. Additionally, patients that receive care at MGH Chelsea HC will be excluded since they already have PN on-site for comprehensive cancer screening.

**Anticipated Enrollment:**
Data from our previous studies of PN (screening for a single cancer at one health center) showed that over a 9 month period, one full time navigator can reach out to approximately 400 patients to navigate them to obtain screening. In this study, we plan to enroll approximately 2500 patients in our 2 study arms (approximately 800 patients in the intervention arm) that will be navigated by 2 FTE TopCare navigators to obtain all 3 cancer screenings.

The survey evaluation outlined in Specific Aim 3 will begin halfway through the 9 month period of the TopCare RCT. Current enrollment rates for the "Improving Comprehensive Cancer Screening Among Vulnerable Patients Using Patient Navigation as Part of a Population-Based Health IT System: A Randomized Control Trial" suggest that nearly 500 patients will meet criteria for interview after receiving PN services in the months of July through December. Based on past experience with similar study design, we anticipate that half of contacted patients will be willing to complete our surveys. We will therefore we will also attempt to contact the same number of patient from the delayed intervention/control group with intention to enroll approximately 250 patients for the PSQ-18 survey.
Specific Aim 1. To modify and improve the existing automated algorithm utilized by TopCare to identify patients who may benefit from PN.

The modification of the automated ‘high risk’ algorithm will focus on using clinically available data to better identify patients who may benefit from PN. The current automated algorithm utilizes information about patient age, number of overdue cancer screening exams, primary language, and no-show visit history. We will explore addition of patient insurance information and education information, as well as other available data, to better identify patients who are likely to not complete screening. We will examine how various iterations of the algorithm correspond with screening completion using data from our prior 1-year randomized trial of the TopCare system in the entire MGPC-PBRN population (Protocol # 2009P002079).

Specific Aim 2. To conduct a randomized trial of the TopCare PN program within our PBRN assessing the impact of PN on cancer screening rates in eligible patients.

**Hypothesis:** Patient navigators using the TopCare system can improve breast, cervical, and colorectal cancer (CRC) screenings across a primary care network.

The TopCare IT system will be modified to allow patients identified as at high risk for not completing cancer screening to be randomly allocated to the intervention or usual care groups. This will involve generating a random number in TopCare at the time a patient becomes overdue. Patients randomly assigned to the intervention group will be eligible for PN, while patients randomly assigned to the usual care group will proceed through TopCare normally without transfer to a PN roster. This may involve physician review, a patient reminder letter, and transfer to a scheduling delegate for follow-up. Control patients at high risk for not completing screening may transfer to the PN roster after the 9-month study period. The randomization scheme will ensure a similar proportion of overdue patients from each practice are allocated to the intervention group. Since Chelsea Health Center has an established PN program, we will exclude this site from randomization and all patients will remain eligible for PN at the health center.

Primary care physicians will still be able to refer patients directly to the TopCare PN and all of them will be navigated. These patients will not be randomized. We expect that this number will be small (less than 60 patients) based upon direct PCP referrals patients to the PN during the TopCare study year.

To ensure an adequate number of patients on the PN roster, modifications to the current TopCare workflow will need to be made. Currently, after a patient is sent a reminder letter, they transfer to a scheduling delegate roster and must remain unscheduled for 4-months before transitioning to the PN roster. In this study, all ‘high risk’ patients on a delegate roster at baseline will be randomized to the intervention or usual care arms. Throughout the 9-month study period, high risk patients assigned to the intervention arm will immediately be placed to the PN roster, while patients in usual care arm will transfer on the scheduling delegate roster as per usual care.
Main outcomes:

a. **Primary Outcome:**
   Average cancer screening test completion rate over the 9-month follow-up period for each eligible patient in all eligible cancers (breast, cervical, and/or colorectal) in 2 study arms

b. **Secondary Outcomes:**

   1) **Primary outcome in specified vulnerable patient subgroups:**
      a) Race/Ethnicity: Hispanic
      b) Primary language: not English
      c) Education level: < high school graduate
      d) Insurance status: Medicaid, no insurance

   2) Average cancer screening test completion rate over the 9-month follow-up period for each eligible patient in each individual cancer (breast cancer—mammography completion, cervical cancer—Pap smear completion, colorectal cancer—colonoscopy, sigmoidoscopy, or CT colonography)

   3) Percentage of patients completing all eligible cancer screening modalities at 9-month follow-up period will be compared between study arms.
      a) Compare results for high risk patients (by study arm) and patients not deemed to be at high risk for not completing cancer screening by the TopCare algorithm.

**Specific Aim 3. To assess the impact of PN on satisfaction with overall medical care.**

**Hypothesis:** Positive PN experiences will improve satisfaction with overall medical care.

We will ask patients who have been randomized to PN early intervention arm to complete two validated surveys: "Satisfaction with Interpersonal Relationships with Navigator (PSN-I)" and "Satisfaction with Logistical Aspects of Navigation (PSN-L)". We will also ask both the PN early intervention group and the delayed intervention group to complete the Short-form Patient Satisfaction Questionnaire (PSQ-18). These surveys will provide information about patient satisfaction with the PN program and information about the impact of the PN program on overall patient satisfaction with medical care.

Participation in this evaluation will be completely voluntary and all subjects will be told of their right to withdraw or end the interview at any time. A fact sheet with the contact information of the study principal investigator will be provided to all survey subjects by mail one week prior to being contacted by telephone (attached) in the event that the subject wants to discuss his/her participation.

Patients will be contacted by telephone and asked to participate if they received PN services as part of the TopCare program during the months July through December 2014, ie, within three months of survey administration. Those interested in participation may then complete the surveys over the telephone or they may elect to complete the surveys in person and will be met by an interviewer at their next MGH clinic appointment. Patient interviews will last approximately 20 minutes in duration (see attached surveys and interview guide). Bilingual
research assistants or trained interpreters will be available to conduct surveys if patients are not native English speakers.

Primary outcomes:

a) Satisfaction with overall medical care as measured by PSQ-18 in two study arms
b) Correlation between satisfaction with PN experience (as measured by PSN-I and PSN-L) and satisfaction with overall medical care (as measured by PSQ-18) in the intervention arm.

Secondary outcomes:

Satisfaction with PN and with overall medical care in specified vulnerable patient subgroups:

a) Race/Ethnicity: Hispanic
b) Primary language: not English
c) Education level: < high school graduate
d) Insurance status: Medicaid, no insurance

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

This study does not involve any specific treatment or diagnosis. Rather, it is using an IT platform which is currently in use at MGH to communicate with patients who appear overdue for preventive cancer screening. Current standard of care for high risk patients involves transition to a PN roster after being on a PCP roster for up to 2 months and after 4 months of remaining unscheduled on a scheduling delegate roster (up to 6-months total wait time). Intervention high risk patients will now immediately transfer to a PN roster after becoming overdue without any delay on a delegate roster. Control high risk patients will proceed normally through TopCare and will be eligible to transfer to a PN list after the 9-month study period.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

The TopCare system is now the standard of care within MGPC-PBRN practices, so patients will not be actively recruited as part of this study. Eligible patients will be identified through data available in the patient’s electronic health record. All patients in both the intervention and control groups will receive care through established providers and practice settings. The intervention will assess the impact of patient navigator use of a computer-based decision support tool to reach out to vulnerable patients across our network. We see no significant risks to patients as a result of the use of this computer-based decision support tool by patient navigators. The system is designed as a fail-safe system that adds to existing methods for preventive cancer screening outreach. The data being collected on outcomes of care are part of the routine data used for patient care and administrative purposes. Uniquely vulnerable populations (fetuses, neonates, children, prisoners, or institutionalized individuals) are not involved in this study.
Verbal consent for participation in study surveys will be obtained either in person or via the telephone by the interviewer. Patients will be informed that participation in their study is entirely voluntary. The risks and benefits of participating in the study are minimal and will be explained in the patient's preferred language. Patients are free to discontinue participation at any time and they may choose not to answer any questions. Patients who continue with the surveys are assumed to have implied consent.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Since all patients will receive standard care through their usual practice setting, the main risk to subjects is a potential breach of patient confidentiality as part of the study procedures that collect unique patient information for the purposes of identifying study participants. Specific procedures are in place and will be continued to minimize this risk. The data being collected are part of the routine data used for patient care and administrative purposes. Uniquely vulnerable populations (fetuses, neonates, children, prisoners, or institutionalized individuals) are not involved in this study. All data will be stored on password-protected computers and clinical data is only accessible to providers with appropriate password authorization. Protected health information (PHI) is only available to authorized clinical providers, and Partners HealthCare Information Systems monitors electronic record review for examination by providers who are not directly involved in a patient’s care. Analyses performed for research purposes will involve additional safeguards. Protected health information will be de-identified during data collection and only uncoded as necessary to link back to patient outcome information. All MGH patients are informed that patient data may be used for clinical research. All identifying patient information will be deleted prior to analysis and data will only be presented in aggregate. Any printed forms with patient data will be stored in a locked cabinet or shredded.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

We see no significant risks to patients as a result of this study. Patients in both intervention (by patient navigators) and control groups (by letter and/or scheduling delegate) will be contacted informing them that they may be due for a preventive cancer screening test as part of standard care. For some individuals this information may cause distress if it is something they are not interested in doing or if they do not think it accurately reflects their particular situation. There are no foreseeable risks from participating in patient surveys except for the time commitment required and the possibility of psychological discomfort in discussing the subject of cancer prevention. Information may also not be up to date for all patients. If an individual believes this is the case, he/she will be provided information about whom to contact to update their records. A standard system is in place as part of usual care to input this information into the patient’s electronic medical record to communicate this information (typically about tests performed
outside of the Partners Healthcare System). All contact with patients, including those in the control group, will be based on current MGH Primary Care guidelines for preventive cancer care.

**EXPECTED BENEFITS**

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, “It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects.” Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

Patients in both the control and intervention arms may benefit from the TopCare application if it results in appropriate preventive cancer screening. Such screening may decrease the individual’s risk of being diagnosed with cancer, or if diagnosed it may be at a stage where treatment is more effective. It is possible that those patients in the intervention group may show increased benefit over patients in the control group since they will be contacted by a patient navigator.

If the intervention is effective in improving care, PN resources may be expanded to reach more vulnerable patients across the primary care network in a more timely manner.

**EQUITABLE SELECTION OF SUBJECTS**

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

All adult patients who are overdue for cancer screening and are deemed at high risk for not completing cancer screening will be eligible for this study (except for patients receiving care at Chelsea HC who have PN available). The selection of intervention patients will be based on a randomization scheme that is intended to distribute patients equally among our primary care practices.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

Patients who do not speak English will be included in this study.

For guidance, refer to the following Partners policy:

Obtaining and Documenting Informed Consent of Subjects who do not Speak English

[http://healthcare.partners.org/phsirb/nonengeo.htm](http://healthcare.partners.org/phsirb/nonengeo.htm)
RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Specific Aims 1 and 2: No patient will be directly recruited for participation in this study and no patient will be directly contacted by study personnel for research purposes. All patient contact in intervention and control groups will be part of clinical care. Eligible patients will be identified by TopCare through electronic review of available data sources (including billing claims, encounter dates, registration data, and information drawn from electronic medical records).

Specific Aim 3: Participants will be mailed an introductory letter with a study fact sheet attached one week prior to being contacted by telephone. Study staff will then contact the patient by telephone to determine if they are interested in participating.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available.

There will be no remuneration for any participants in this study.

For guidance, refer to the following Partners policies:
- Recruitment of Research Subjects
  http://healthcare.partners.org/phsirb/recruit.htm
- Guidelines for Advertisements for Recruiting Subjects
  http://healthcare.partners.org/phsirb/advert.htm
- Remuneration for Research Subjects
  http://healthcare.partners.org/phsirb/remun.htm

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators’ own patients, describe how the potential for coercion will be avoided.
We are requesting a waiver of written consent. Patient navigation has been a standard of care at MGH for a decade. TopCare system PN has been used for almost 2 years. However, due to limited resources, we can not provide navigation to all high risk patients at MGH in a timely manner. This study will provide navigation to up to about 800 patients over 9 months (data from the completed TopCare clinical trial showed that 420 were contacted by a single full-time patient navigator over 1-year) as a part of an early intervention group. All other patients will receive usual care and be offered navigation after 9-months period.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
http://healthcare.partners.org/phsirb/newapp.htm#Newapp

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects
http://healthcare.partners.org/phsirb/infcons.htm

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

Because potential risks to patients are minimal, patients will receive standard care, and the period of intervention short, we do not plan to employ a Data Safety Monitoring Board and have chosen not to employ formal interim analyses or guidelines for early termination of this short trial. In the event that adverse events are found to occur more often in either study group, we will alert the Partners HealthCare System IRB as soon as we are aware and take further action as needed.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners’ IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners’ IRBs. When the investigator is also the sponsor of the IND/IDE, include
the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting.

The PI will report adverse events or other unanticipated problems to the PHRC as described in the PHRC policy on Adverse Event Reporting and Unanticipated Problems Involving Risks to Subjects or Others.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

All study personnel are experienced clinical investigators and have completed required IRB-related programs. Study investigators and research personnel have extensively used data sources as part of clinical quality improvement and research activities that will be employed in this study. Regular meetings involving study investigators and staff will be held to ensure the validity, integrity, and timeliness of the data, and adherence to the IRB-approved protocol and Partners Human Research Committee policies.

For guidance, refer to the following Partners policies:
- Data and Safety Monitoring Plans and Quality Assurance
  [http://healthcare.partners.org/phsirb/datasafe.htm](http://healthcare.partners.org/phsirb/datasafe.htm)
- Adverse Event Reporting Guidelines
  [http://healthcare.partners.org/phsirb/adverse_events.htm](http://healthcare.partners.org/phsirb/adverse_events.htm)

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data;
use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

All data will be stored on password-protected computers, and personal health information will be de-identified during data collection and only decoded as necessary to link back to patient outcome information. Only IRB approved study personnel will perform and have access to confidential patient data. All data sources used as part of this study are maintained by MGH and Partners and meet current HIPAA requirements. All MGH patients are informed that patient data may be used for clinical research. All identifying patient information will be deleted prior to analysis and data will only be presented in aggregate. Any printed forms with patient data will be stored in a locked cabinet or shredded.

**SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS**

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

No specimens or data will be sent to research collaborators outside Partners.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

No specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol.

**RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS**

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

No specimens/data will be collected outside of Partners.